K072272
p1/1

510(k) Summary for Honeywell HomMed Central Station version 4.0

Submitter:	Honeywell HomMed, LLC
Address:	3400 Intertech Drive, Suite 200 Brookfield, Wisconsin 53045
Corporate Contact:	Michael Leigh, Director of Regulatory/Quality Honeywell HomMed, LLC
Telephone:	Ph: (262) 783-5440 Fax: (262) 783-5441
Establishment Registration #:	3004183721
Submission Contact:	Michael Leigh, Director of Regulatory/Quality Honeywell HomMed, LLC 3400 Intertech Drive, Suite 200 Brookfield, Wisconsin 53045 Ph: (262) 252-5794 Fax: (262) 252-6105
Trade Name:	Central Station, Version 4.0
Predicate Device:	HomMed Central Station, Version 3.5, K053453
Common Name:	Patient Vital Signs Monitor Viewing Station
Classification Name:	Non-Invasive Blood Pressure Measurement System Product Code: DXN

SEP - 7 2007

Intended Use:

Central Station's intended use is to retrospectively receive; display and store monitored vital signs parameters and related data. Central Station displays the data and system alerts for review and evaluation by a healthcare professional. Central Station is not intended for emergency use or real-time monitoring.

Performance Data:

Central Station is a software system that operates on a commercially available PC system with the minimum performance specifications consistent with typical PC hardware and equipment specifications. Central Station accepts data from Honeywell HomMed Patient Monitors (e.g. Sentry and Genesis) as well as the Honeywell HomMed MedPartner. The software validation results demonstrated that the Central Station System was in compliance with the guidelines and standards referenced in the FDA reviewer's guides and that it performed within its specifications and functional requirements for software.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of FDA regarding medical device software.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 7 2007

Honeywell HomeMed, LLC
c/o Mr. Michael Leigh
Director of Regulatory/Quality
3400 Intertech Drive, Suite 200
Brookfield, Wisconsin 53045

Re: K072272
Central Station, Version 4.0
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: August 13, 2007
Received: August 15, 2007

Dear Mr. Leigh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zimmerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K07227

Indications for Use

510(k) Number (if known):

Device Name: Honeywell HomMed Central Station 4.0

Indications For Use:

Central Station's intended use is to retrospectively receive, display and store monitored vital signs parameters and related data. Central Station displays the data and system alerts for review and interpretation by a healthcare professional. Central Station is not intended for emergency use or real-time monitoring.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K07227